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Date:

March 5, 2008

Sean Mellino

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant : Christian Von Falkenhausen, et al.  
Serial No. : 10/517,087 (Confirmation No. 1143)  
Filing Date : December 6, 2004  
Examiner : Darryl C. Sutton  
Group Art Unit : 1614  
Title : ACTIVE SUBSTANCE-CONTAINING FILM-  
LIKE PREPARATIONS HAVING IMPROVED  
CHEMICAL STABILITY, AND PROCESSES FOR  
THEIR PREPARATION  
Attorney File : RO0937US (#90568)

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**Reply to Office Action Issued December 19, 2007**

Dear Sir:

Claims 1-29 are pending in the instant application. The Examiner has concluded that restriction to one of the following three groups is necessary:

- I. Claims 1-12, 14 and 19-26, drawn to a composition with a maximum peroxide number of 40 for application in the oral cavity releasing active substances transmucosally.

- II. Claims 1-11, 13, 14 and 19-26, drawn to a composition with a maximum peroxide number of 40 for application in the oral cavity releasing active substances through the gastrointestinal tract.
- III. Claims 15-18 and 27-29, drawn to a method for manufacturing a composition for application in the oral cavity or for transmucosal application.

The Examiner explains in the Office action that the inventions of Groups I-III do not relate to a single general inventive concept because they lack the same or general technical features since there is no special technical feature in the present claims. In particular, the Examiner explains on page 3 (first paragraph) of the Office action that the technical feature that is set forth in Groups I and II is a composition which comprises a film-like active ingredient for application in the oral cavity or transmucosal application and that Group III discloses a method for manufacturing a composition comprised of a film-like active ingredient, which comprises determining a peroxide number, selecting components, preparing a solution and coating the solution. In other words, the Examiner states that Group III contains active physical steps of manufacture while Groups I and II include components together in a static composition. Since Group III has active steps and Groups I and II do not share the same methods of application, the Examiner concludes that Groups I, II and III do not share a common technical feature and thus the claims lack unity.

The Examiner also concludes that this application contains claims which are directed to more than one species of the generic invention (as explained on page 3 of the Office action) and therefore these species lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The Examiner

considers the species of this application to be the (a) oxygen-containing compounds, (b) antioxidants, (c) mono-layer or multiple layers of polymer matrix, (d) polymers, (e) additives, (f) active substances, (g) coating methods and (h) reducing agent. In particular, the Examiner concludes that the species lack the same or corresponding technical features since the oxygen-containing species can differ in their interactions with the matrix; antioxidants vary in structure and therefore in their antioxidant capabilities; the interaction of the active ingredients with a mono-layered or multilayered matrix will not be the same; the polymers have distinct structures; the additives have different functions in the composition; the active substances can have different physiological action; the coating methods produce distinct coatings; and reducing agents vary in structure, and therefore in their reducing capabilities.

The Applicants hereby elect the claims of Group I (which reads on claims 1-12, 14 and 19-26, drawn to a composition with a maximum peroxide number of 40 for application in the oral cavity releasing active substances transmucosally) for further prosecution on the merits thereof. The Applicants also elect the single species as follows:

- (a) oxygen-containing compound or compounds: hydrogen peroxide
- (b) at least one antioxidant: tocopherols
- (c) either mono-layer or multiple layer: mono-layer polymer matrix
- (d) at least one polymer: cellulose ether
- (e) at least one additive: permeation-enhancing substances
- (f) at least one active substance: nicotine

However, the Applicants respectfully object to the instant restriction requirement, with

traverse, as discussed below.

The Applicants respectfully submit that the inventions set forth in the three aforementioned groups relate to a single general inventive concept. In particular, the inventions according to Groups I and II differ by the way the location the active substances that are contained in the compositions are to be released (in the oral cavity (Group I) or in the gastrointestinal tract (Group II)). However, it should be appreciated by one skilled in the art that these are not the technical features of the composition. This information actually determines the purpose for which the compositions are intended. Any such purposes do not affect the technical features of the product, nor do such purposes determine the scope of protection provided by a product claim.

It is further submitted that finding no single general inventive concept for the compositions according to Group I and Group II might be considered reasonable if the claims of both groups would have been directed to methods of treatment. However, the claims of both Groups I and II are product claims rather than method claims, while the claims of Group III are directed to a method of manufacturing the compositions of Groups I and II.

The Applicants also submit that the general inventive concept is to provide film-like active substance-containing preparations possessing improved stability of the active substance contained in the preparations. This is achieved in that the film-shaped active substance-containing preparations do not have a peroxide number of more than 40. It is therefore submitted that the peroxide number is a technical feature that is closely

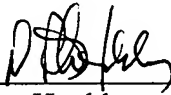
associated with the components that are employed for manufacturing the film-like active substance-containing preparation of the present invention.

In view of the above arguments, withdrawal of the present restriction requirement is respectfully requested.

The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

Date: March 5, 2008

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